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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,452	03/18/2005	Kyoichiro Iida	00005.001256.	4898
5514 7590 03/09/2009 FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK NY 10112			EXAMINER	
			QAZI, SABIHA NAIM	
NEW YORK, P	V YORK, NY 10112		ART UNIT	PAPER NUMBER
			1612	
			MAIL DATE	DELIVERY MODE
			03/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)					
Office Action Comment	10/528,452	IIDA ET AL.					
Office Action Summary	Examiner	Art Unit					
	Sabiha Qazi	1612					
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	l. ely filed the mailing date of this communication. O (35 U.S.C. § 133).					
Status							
1) Responsive to communication(s) filed on							
	-· action is non-final.						
3) Since this application is in condition for allowar		eccution as to the morits is					
closed in accordance with the practice under <i>E</i>							
closed in accordance with the practice under £	x parte Quayle, 1955 C.D. 11, 45	3 O.G. 213.					
Disposition of Claims							
4)⊠ Claim(s) <u>1-37</u> is/are pending in the application.							
4a) Of the above claim(s) is/are withdrav	vn from consideration						
5) Claim(s) is/are allowed.							
6) Claim(s) is/are rejected.							
7) Claim(s) is/are objected to.							
8)⊠ Claim(s) <u>1-37</u> are subject to restriction and/or e	election requirement.						
Application Papers							
9)☐ The specification is objected to by the Examine	r.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the	· · · · · · · · · · · · · · · · · · ·						
Replacement drawing sheet(s) including the correcti		• •					
11) The oath or declaration is objected to by the Ex		, ,					
TT) The Oatif of declaration is objected to by the Ex	animer. Note the attached Office	ACTION OF TOTAL					
Priority under 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents</li> <li>2. Certified copies of the priority documents</li> <li>3. Copies of the certified copies of the prior application from the International Bureau</li> <li>* See the attached detailed Office action for a list of the certified copies of the attached detailed Office action for a list of the certified copies of the prior application from the International Bureau</li> </ul>	s have been received. s have been received in Application ity documents have been received (PCT Rule 17.2(a)).	on No d in this National Stage					
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal P 6)  Other:	te					

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## **DETAILED ACTION**

Claims 1-37 are pending, preliminary amendments filed on 3/18/2005 are entered.

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-28 are drawn to [1,3,4]triazolo[1,5c]pyrimidine compounds of formula (I) when R3 represents formula (A3).

Group II, claims 1-28 are drawn to compounds of formula (I) when R3 represents formula (B1).

Group III, claims 1-28 are drawn to compounds of formula (I) when R3 represents formula (C3).

Group IV, claims 1-28 are drawn to compounds of formula (I) when R3 represents formula (E1).

Group V, claims 1-28 are drawn to compounds of formula (I) when R3 represents formula (F1).

Group VI, claims 1-28 are drawn to compounds of formula (I) when R3 represents formula (A4).

Group VII, claims 1-28 are drawn to compounds of formula (I) when R3 represents formula (A3).

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Group VIII, claims 1-28 are drawn to compounds when R3 is other than (A3), (B1), (C3), (E1), (F1), (A4), (A3).

Group IX, claims 26-37 are drawn to method of using the compounds.

The inventions listed as Groups I to VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. The compounds and process of making as claimed in groups I to VIII contain different core with different chemical structures and therefore lack unity of invention. Each formula includes large number of compounds.

The compounds represented by general formula (I) in claim 1 share the structural feature of a 2-(aromatic)-5- (secondary amine)-[1,2,4] triazolo [1,5-c]pyrimidine derivatives of formula (I) is a partial structure and is not novel because they disclosed in the references cited in the specification. Therefore, no technical relationship involving a "special technical feature" can be established among the compounds containing triazolo-pyrimidine group. Therefore, the invention as claimed cannot be considered to be so linked as to form a single general inventive concept.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Annex B of the PCT Administrative Instructions contains the following guidance with respect to Markush group claims when determining Unity of Invention:

(f)(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) all alternatives have a common property or activity, and
- (B) (1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or
- (B) (2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.
- (ii) In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.
- (iii) In paragraph (f)(i)(B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

(iv) The fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention

The examiner in making a Lack of Unity holding has divided the Markush Group into a number of different Groups based on lack of a special technical feature defined as lacking a significant structural element which defines over the art. The examiner has held that the significant structural element, the **steroid** structure, does not define over the art.

1. Due to complexity of the invention no call was made to request the election.

Applicant is required, in reply to this action, to elect a single species from the elected group for the search purposes to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

2. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features. Applicant is requested to elect a single species from the elected group for the search purposes.

## Restriction to Common Core

This application contains claims directed to patentably distinct inventions (NOT species) as follows: each of the specifically claimed core compounds encompassed by claimed compounds for example heteroatoms is selected from O, and N as defined for D in formula (I), see also the reasons cited above. Furthermore, claims are drawn to different compounds having different core because of different chemical structures, which lack unity of invention as the compounds have no substantial structural similarities although they have a common utility. In re Harnisch, 631 F.2d 716, 206 USPQ 300(CCPA 1980); Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Thus, Applicant is advised that a reply to this requirement must include an identification of the invention and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

In summary, applicant should elect ONE COMMON CORE. *Election of Species of Substituents* 

Applicant should note that selection of ONE COMMON CORE is for RESTRICTION purposes. Once a common core has been elected, applicant will be further required to elect one specific chemical compound having that core.

Again, applicant should note that selection of this specific compound is an election of species, not a restriction. Accordingly, should a particular elected compound be found free of prior art, the search will be extended to additional non-elected substituents on said core.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. <u>All</u> claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim

will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

## **Communication**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/

Primary Examiner, Art Unit 1612